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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/046,833	03/24/98	LIU	D ENZ-56 (DIV4)

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HM22/0526

EXAMINER

GUZO, D

ART UNIT	PAPER NUMBER
1636	7

DATE MAILED:

05/26/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 3/10/99
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three (3) month(s), or ~~thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 68-74 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 68-74 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 68-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Salmons et al. or Smith et al.

This rejection is maintained for reasons of record in the previous Office Action (Paper # 4) and for reasons outlined below. The rejection is expanded to include new claims 69-74 as a result of applicants' amendment filed 3/10/99.

Applicants traverse this rejection by asserting that the amended claim 68 and new claims 69-74 (which depend from claim 68) are not taught by Salmons et al. or Smith because neither reference teaches the claimed feature wherein the nucleic acid component and the non-nucleic acid component are capable of forming a specific complex with each other. Applicants subsequently argue that the useful properties of the invention as now claimed involve localization to defined regions of a nucleic acid construct, reduction or elimination of potential interference with region segments in the nucleic acid constructs, etc.

Applicants' remarks filed 3/10/99 have been carefully considered but are not deemed persuasive. First, the newly added limitation concerning "...said nucleic acid component and said

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non-nucleic acid component being capable of forming a specific complex..." reads on a nucleic acid component of a vector and a protein component of a viral vector particle, i.e. a retroviral vector nucleic acid molecule and a gag, env or pol protein molecule. Given this reading of the claim language, Salmons et al. and Smith both recite packaging cell lines which comprise a viral (retroviral) vector comprising a nucleic acid component and a non-nucleic acid component (i.e. gag, env or pol) being capable of forming a specific complex with each other in the context of a viral vector particle.

Second, with regard to newly added claims 69-74, both Salmons et al. and Smith teach retroviral vector packaging cell lines which can be derived from cells "native" to the viral vector, i.e. Ψ -2 cells or Ψ -am or PA317 etc. cells and wherein the viral vector nucleic acid component can be native or non-native (i.e. having endogenous or heterologous expression control sequences, etc.) to the vector and wherein the viral vector nucleic acid component consists of genomic viral DNA (i.e. provirus) or fragments of said DNA. With regard to the packaging cell expressing on its membrane a member which can be a non-native viral vector nucleic acid component, etc., it is noted that both Salmons et al. and Smith teach the construction of pseudotyped retroviral vectors wherein the packaging cells express on their membrane a non-native viral vector nucleic acid component. Therefore, Salmons et al. and Smith both teach the claimed invention.

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 68-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 (and dependent claims) is vague in the recitation of the phrase "capable of forming a specific complex" since the capacity of a compound or composition to perform some function is merely a recitation of a latent characteristic of said composition or compound and said language carries no patentable weight, i.e. it is unclear under what conditions the compounds can form a specific complex and under what conditions they cannot.

Claims 71-73 are vague with regard to the viral vector nucleic acid being native or non-native to the vector. Since the claimed viral vectors can be composed of components from two or more sources, language reading on components "native" or "non-native" to the vector has no meaning since the context of the terms "native" or "non-native" is unclear.

With regard to the Sequence Listing Requirement, it is noted that the Sequence Listing in the parent application (S.N. 08/822,963) has not been submitted in an acceptable form and no Sequence Listing file for the 08/822,963 application exists. Since no file for the parent exists

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applicants must submit a Sequence Listing for the instant application, or if a suitable Sequence Listing is eventually filed in the parent application, applicants may rely upon that CRF to prepare a file for the offspring. Any response to this Office Action that does not address this issue will be considered non-responsive.

No Claims are allowed.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
May 24, 1999

DAVID GUZO
PRIMARY EXAMINER

